

# Certificate

**ECM – Zertifizierungsgesellschaft  
für Medizinprodukte in Europa mbH,**  
Talbotstraße 21, 52068 Aachen, Germany

hereby declares that an examination according to  
DIN EN ISO/IEC 17021-1:2015 of the undermentioned  
quality assurance system has been carried out.



Through an audit performed on behalf of

**TRIGOcare International GmbH**  
In den Wiesen 3 , 51674 Wiehl, Germany

it could be demonstrated that a quality management system  
according to

**ISO 13485:2016**  
**EN ISO 13485:2016 + AC:2018 + A11:2021**  
**DIN EN ISO 13485:2021**

„Medical devices – Quality management systems – Requirements for  
regulatory purposes“

for the scope:

**import and distribution of medical devices for wound  
care and plaster products**

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report  
for the audit mentioned below.

Any substantial changes of the quality management system have to be  
notified to ecm and are subject to a separate assessment.

Audit-No.	Registered under	Valid until
<b>0539-24-1030</b>	<b>Z/25/04882E</b>	<b>30 March 2028</b>

Valid as of: 31 March 2025

  
Certification body

